UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, Plaintiff, v. MIRA HEALTH PRODUCTS LTD., a corporation MICAEL S. RAGNO, an individual MICHAEL S. RAGNO, JR., an individual Defendants.	CIVIL ACTION NO._____ COMPLAINT FOR PERMANENT INJUNCTION

CV-14 3549

BIANCO, J.

BROWN, M. J.

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to enjoin and restrain Michael S. Ragno and Michael S. Ragno, Jr., individuals, and Mira Health Products Ltd., a corporation, from violating: (a) 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce articles of food (dietary supplements) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1); and (b) 21 U.S.C. § 331(k), by causing articles of food (dietary supplements) that Defendants hold for sale after shipment in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(g)(1).

JURISDICTION AND VENUE

2. This Court has jurisdiction under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331 and 1345.

3. Venue in this District is proper under 28 U.S.C. §§ 1391(b) and (c).

DEFENDANTS

4. Defendant Mira Health Products Ltd. ("Mira") is a New York corporation that manufactures, processes, packs, labels, holds, and distributes dietary supplements. Mira is located at 65 E. Carmans Road, Farmingdale, New York, within the jurisdiction of this Court.

5. Defendant Michael S. Ragno is Mira's owner and Chief Operating Officer. Mr. Ragno is the most responsible person at Mira. His duties include overseeing all manufacturing operations, marketing, and training, and he performs these duties at 65 E. Carmans Road, Farmingdale, New York, within the jurisdiction of this Court.

6. Defendant Michael S. Ragno, Jr. is Mira's quality assurance/quality control ("QA/QC") manager. His responsibilities include overseeing: receipt of raw materials; manufacturing operations; and QA/QC. Mr. Ragno, Jr. performs his duties at 65 E. Carmans Road, Farmingdale, New York, within the jurisdiction of this Court.

7. Defendants have been engaged in manufacturing, processing, packing, preparing, labeling, holding, and distributing products including, but not limited to, Bolasterol, Dym-sdrol, Metha-drol, Super DMZ, Bolt: Fat Incinerator, Libigrow, Mojo Nights, Health Life Chemistry By Purity First Vitamin C-500, Health Life Chemistry By Purity First Multi-Minerals, Green Phactor Powder Greens, Simply Weight Loss Carbo-Block, and Simply Weight Loss Stabilizer Fat Inhibitor. Defendants manufacture their products using components they receive in interstate commerce. Defendants distribute their products in interstate commerce to locations outside the state of New York, such as Georgia, North Carolina, and New Jersey.

DEFENDANTS MANUFACTURE AND DISTRIBUTE ADULTERATED DIETARY SUPPLEMENTS

8. The Act defines "dietary supplement" as "a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract or combination of [any of the preceding ingredients]." 21 U.S.C. § 321(ff). In addition, a dietary supplement must not be "represented for use as a conventional food or as a sole item of a meal or the diet" and must be "labeled as a dietary supplement." Id. Dietary supplements are deemed to be "food" under the Act, except for purposes of 21 U.S.C. §§ 321(g) and 350f. Id.

9. Defendants' products are labeled as dietary supplements on their principal display panels, as defined in 21 C.F.R. § 101.1. Furthermore, each of Defendants' products contain at least one of the dietary ingredients specified in 21 U.S.C. § 321(ff).

10. The Act requires dietary supplement manufacturers to operate in compliance with the current good manufacturing practice requirements for dietary supplements ("Dietary Supplement cGMP"). 21 U.S.C. § 342(g)(1). Manufacturing according to Dietary Supplement cGMP means that the manufacturing process incorporates a set of controls in the design and production processes to ensure a quality finished product. Dietary supplements that are not manufactured, prepared, packed, and held in conformance with Dietary Supplement cGMP are deemed to be adulterated. 21 U.S.C. § 342(g)(1). The Dietary Supplement cGMP regulations are set forth at 21 C.F.R. Part 111.

11. FDA's July 9 – 17, 2013 inspection of Defendants' facility (the "July 2013 inspection") establishes that the dietary supplements that Defendants distribute are adulterated within the meaning of 21 U.S.C. § 342(g)(1), in that they were prepared, packed, and held in a

manner that does not conform to Dietary Supplement cGMP. Defendants' significant deviations from Dietary Supplement cGMP, include, but are not limited to, the following:

a. Failure to conduct at least one appropriate test or examination to verify the identity of a dietary ingredient prior to its use, as required by 21 C.F.R. § 111.75(a)(1)(i). Specifically, Defendants do not conduct identity testing on any dietary ingredients prior to their use in manufacturing dietary supplements;

b. Failure to qualify a supplier of a non-dietary component prior to using the component to manufacture dietary supplements, as required by 21 C.F.R. § 111.75(a)(2)(ii). Specifically, Defendants have not qualified any of their suppliers' certificates of analyses by confirming the results of such suppliers' tests or examinations.

c. Failure to verify that a finished batch of dietary supplements meets product specifications for identity, purity, strength, composition, and for limits on those types of contaminants that may adulterate or that may lead to adulteration of the finished batch of dietary supplement, as required by 21 C.F.R. § 111.75(c). Specifically, Defendants send finished products for microbial testing, but they do not verify that their finished batches of dietary supplements meet product specifications for identity, purity, strength, and composition.

d. Failure to include complete information relating to the production and control of each batch in batch production records, as required by 21 C.F.R. § 111.255(b). Specifically, Defendants failed to include the following information in the batch production record for Mineral Complex: the pre-encapsulation checklist; information about the capsule used in production; the pre-packing and labeling checklists; bottling count chart; documentation that quality assurance approved the product label; documentation of final product sampling; and documentation of final review by the QA/QC team.

e. Failure to ensure that manufacturing, labeling, and holding operations ensure the quality of the dietary supplements and that the dietary supplements are packaged and labeled as specified in the master manufacturing record, as required by 21 C.F.R. § 111.105. Specifically, Defendants' quality control personnel did not review batch records for completeness and accuracy prior to releasing certain finished dietary supplements, such as Mineral Complex and Uriflow.

f. Failure to hold components, dietary supplements, packaging, and labels under conditions that do not lead to their mix-up, contamination, or deterioration, as required by 21 C.F.R. § 111.455(c). Specifically, Defendants' raw materials, in-process materials, quarantined materials, and finished products are not clearly identified.

HISTORY

12. Defendants have a history of violating the Act. Several of the Dietary Supplement cGMP deviations observed during the July 2013 inspection (referenced in Paragraph 11 above) are the same as, or similar to, those observed by FDA during inspections of Defendants' facility between March 13-23, 2012, and between March 18-22, 2013. For example, during both the March 2013 and 2012 inspections, FDA documented that Defendants failed to establish that their suppliers' certificates of analyses were reliable by confirming the results of their suppliers' tests or examinations (similar to Paragraphs 11(a)-(b) above). FDA also documented Defendants' failure to verify that finished batches of dietary supplements met product specifications for identity, purity, strength, and composition (similar to Paragraph 11(c) above) during the March 2013 inspection. FDA also documented Defendants' failure to hold components, dietary supplements, packaging, and labels under conditions that do not lead to their

mix-up, contamination, or deterioration (similar to Paragraph 11(f) above) during the March 2013 inspection.

13. FDA has repeatedly warned Defendants about their ongoing Dietary Supplement cGMP violations. At the close of the March 2013 inspection, FDA investigators issued a list of Inspectional Observations ("Form FDA-483") to, and discussed each of the observed deviations with, Defendants Michael S. Ragno and Michael S. Ragno, Jr. Defendants responded to FDA in writing with promises to correct the Dietary Supplement cGMP violations. In addition, at the close of the March 2012 inspection, FDA investigators issued a Form FDA-483 to Defendant Michael S. Ragno. Defendants responded to FDA in writing with promises to correct the Dietary Supplement cGMP violations. Although Defendants made some corrections in response to FDA's inspection observations, they either did not follow through on their attempts to correct or failed to sustain the corrections they made, as shown by the ongoing, significant Dietary Supplement cGMP violations observed during the July 2013 inspection of Defendants' facility.

14. Based on the foregoing, Plaintiff believes that, unless restrained by this Court, Defendants will continue to violate the Act in the manner set forth above.

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, from doing or causing to be done, any of the following acts:

A. Violating 21 U.S.C. § 331(a), by distributing adulterated food (dietary supplements) in interstate commerce; and

B. Violating 21 U.S.C. § 331(k), by causing food (dietary supplements) that Defendants hold for sale after shipment interstate commerce to become adulterated;

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from manufacturing, processing, packing, labeling, holding, or distributing dietary supplements, unless and until Defendants' methods, facilities, and controls used to manufacture, process, pack, label, and hold dietary supplements are established, operated, and administered in conformity with Dietary Supplement cGMP and the Act, in a manner that has been found acceptable by FDA;

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' place(s) of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any dietary supplement to ensure continuing compliance with the terms of the injunction, the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. That Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

DATED this 5th day of June, 2014.

Respectfully submitted,

LORETTA E. LYNCH
United States Attorney

By: _____
Thomas A. McFarland
Assistant U.S. Attorney

U.S. Attorney's Office
610 Federal Plaza, 5th Floor
Central Islip, NY 11722-4454
Tel.: 631-715-7863
Fax: 631-715-7920

MICHAEL S. BLUME
Director

By: _____
Melanie Singh
Counsel
Consumer Protection Branch
Department of Justice, Civil Division
P.O. Box 386
Washington, D.C. 20044
Tel.: (202) 616-9928
Fax: (202) 514-8742

Of Counsel:

WILLIAM B. SCHULTZ
General Counsel

ELIZABETH H. DICKINSON
Chief Counsel
Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel for Litigation

CHRISTOPHER A. FANELLI
Assistant Chief Counsel for Enforcement
United States Department of Health and Human Services
Office of the General Counsel
Food and Drug Administration
10903 New Hampshire Avenue
WO 31-4581
Silver Spring, MD 20993
301-796-8559